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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,032	03/30/2000	Samir Kumar Brahmachari	07064-01001	7985

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EXAMINER
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MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/05/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/539,032

Applicant(s)

BRAHMACHARI ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 1,3,4,6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and objections not repeated below are hereby withdrawn.

### ***Specification***

The disclosure is again objected to, as previously set forth in the Office Action of 10/28/02 because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant states in the response filed 3/10/03 "that the embedded hyperlink has been deleted from the specification"; however, as no amendment to the specification has been filed, the embedded hyperlinks have not been deleted. Further, it is noted that hyperlinks are found on at least three different pages of the specification (pp. 7, 9, and 13). Applicant is required to remove ALL hyperlinks from the specification, including any not specifically enumerated herein. As the hyperlinks have not been deleted, the objection is maintained.

### ***Claim Objections***

Claims 1, 3-4, 6 and 8 are objected to because of the following informalities. Step (viii) of claim 1 recites "a given conserved sequences", which is grammatically incorrect.

Claim 3 limits a selected organism to be "at least one" from a selected list; however, the members of the list are not connected by a conjunction. This is improper claim construction. This objection may be overcome by inserting --and--before "Escherichia" in line 2 of claim 3.

Claim 4 limits a sequence to "include one or more of" a list of sequences; however, the members of the list are not joined by a conjunction. This is improper claim construction. This objection may be overcome by inserting --and--before the last element of the list.

Claim 6 limits a sequence to "belong to at least one of" a list of proteins; however, the members of the list are not joined by a conjunction. This is improper claim construction. This objection may be overcome by inserting --and--before the last element of the list.

Claims 4 and 6 do not end with a period.

The third "step" of claim 8 added in amendment appears to be a run-on "sentence" in construction and is somewhat difficult to read. Applicant is requested to add appropriate punctuation (e.g. commas and/or semicolons) to separate the intended limitations. In addition, claim 8 recites the term "PID" in line 6. The specification defines this term as the abbreviation for "protein identification number" on page 15, therefore the term is not indefinite. For greater clarity, however, the full term should be fully recited at least once in the claims.

Appropriate correction of all claims is required.

### ***Claim Rejections - 35 USC § 112***

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites the term "proteome" in steps (vii) and (viii). The term "proteome" is not defined by the specification or in the claims and may have several meanings in the art; e.g. all of the proteins expressed by an organism, the protein set associated with a particular metabolic function or with a cascade of reactions, the protein set associated with a particular cell type, or with a particular tissue, the protein set expressed at a particular developmental stage, etc. As applicant does not define the term, and it is not clear which of the several meanings applicant intends for the term "proteome", one skilled in the art would not know the metes and bounds intended by applicant for the term, therefore the claim is indefinite.

Applicant is advised that if the intended meaning is "all of the proteins expressed by an organism", then the claims may not be fully enabled as the "proteome" of many eukaryotic hosts are not known. However, as it is unclear what meaning applicant actually intends, the claims are rejected herein only for indefiniteness.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential cooperative relationships of elements, such omission amounting to a gap between the necessary cooperative connections. See MPEP § 2172.01. The omitted cooperative relationships are as follows: Amended claim 1 recites steps (i) to (vi) of identifying/generating and structurally annotating extended conserved sequences from selected organisms. It is noted that these organisms are not limited to be infective, pathogenic, nonpathogenic, microbial in origin, etc. Amended claim 1 also recites a step (vii) of comparing pathogenic and nonpathogenic proteomes and selecting a conserved sequence "not commonly conserved" in these two groups. The claim does not recite any connection between the first 6 recited steps and step (vii). It is not clear if the "conserved sequence" selected in step (vii) is intended to be one of the group of extended conserved sequences identified in the earlier steps, or is intended to be a conserved sequence identified by a different method, or one previously known in the art. Further, it is unclear what the relationship, if any, is between the "selected organisms" of step (i) and the pathogenic and non-pathogenic "strains" of step (vii). Further, claim 1 recites a step (viii) of validating "at least one conserved sequence" by searching for a conserved sequence (or for conserved sequences) in a host proteome. It is not clear what the relationship is between this step and any previous step. Is the "at least one conserved sequence" one of the "extended conserved sequences" of steps (i)-(v)? What is the relationship between the comparison between "strains" of step (vii) and the validation/search of a host

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proteome of step (viii)? As the connection between steps is unclear, there is a gap between the elements of the claim, and the claim is indefinite.

Claim 6 recites the limitation "the invariant sequences" in line 2. There is insufficient antecedent basis for this limitation in the claims, therefore claim 6 is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Amended claim 1 recites comparison of proteomes, which is new matter. Neither the originally filed specification or claims recite the actual term "proteome" anywhere. As set forth above, the term is not specifically defined anywhere. Originally filed claim 1 recited steps of genome comparison between pathogenic and nonpathogenic microbes and between a microbial sequence and a host genome. While original claim 1 also recited steps of identifying and elongating conserved peptide sequences, there is no indication in original claim 1 that entire SETS of proteins (i.e. some sort of proteome) were to be compared.

The originally filed specification teaches, on page 2, that the inventive method is one for genome-wide comparison of a large number of protein sequences, and on page 4, that peptide motifs may be identified by direct sequence comparison between bacterial genomes. A

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comparison of all proteins predicted to be expressed from a genome MAY be interpreted to be a comparison of proteomes; however, the originally filed specification does not clearly disclose such a step. The specification also discloses that a program called PEPLIMP is to be used to compare protein libraries of organisms selected by a user. Again, it is not specifically disclosed, and not made clear, whether the "protein libraries" are intended to be "proteomes". Example 2 of the specification, on page 14, discloses a comparison of nonpathogenic and pathogenic peptide libraries; however, this step appears to occur BEFORE any labeling, overlapping, elongation, or structure annotation steps (as disclosed in Examples 3-5), therefore it does not appear that this can be the same as step (vii) of the method of claim 1. Again, it is not specifically disclosed, or made clear, whether the peptide libraries compared in the Examples of the specification are intended to be "proteomes".

There is no disclosure in the specification for comparison of a host proteome, peptide library, or any other protein "set" to an infective organism's proteome, peptide library or other protein "set". The specification discloses in Example 7, on page 16, that DNA gyrase is found in bacteria but is not known in humans; however, no actual step of comparing any peptides between humans and bacteria is disclosed. The conclusion stated in Example 7 may be general knowledge, or may be known to applicants from previous studies, or may be a conclusion based on a text search of a reference database, etc.

In the response filed 3/10/03, applicant does not point to any support in the originally filed specification or claims for steps of comparing proteomes, and none is apparent, as set forth above, therefore the claims are rejected for reciting new matter.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

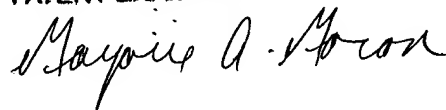
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER



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